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Bruce L. Gibbins

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Ballard Spahr LLP

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GHALI, ISIS A D

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/752,939	Applicant(s) GIBBINS ET AL.	
	Examiner Isis A. Ghali	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,6,8,21,23-28,31-35,38-43,45-59 and 61-72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,6,8,21,23-28,31-35,38-43,45-59 and 61-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The receipt is acknowledged of applicants' amendment filed 12/03/2009.

Claims 3, 5, 7, 9-20, 22, 29, 30, 36, 37, 44, 60 have been canceled.

Claim 72 is currently added.

Claims 1, 2, 4, 6, 8, 21, 23-28, 31-35, 38-43, 45-59, 61-72 are pending and included in the prosecution.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1, 2, 4, 6, 8, 21, 23-28, 31-35, 38-43, 45-59, 61-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murdock (US 2002/0042587) in view of Marans (US 3,511,764) and Ladin (US 5,792,090).

Applicant's claims

Claim 1 as currently presented: An oxygen-delivery matrix, comprising a biocompatible, single unit matrix capable of delivering oxygen, comprising a) a swellable, cross-linked polyacrylamide polymer network, b) deliverable oxygen in closed

cells within the cross-linked polyacrylamide polymer network wherein after the polyacrylamide polymer network is cross-linked, the closed cells are formed by oxygen by reacting the catalyst and a second reactant, and wherein with use of the matrix, oxygen is delivered from the closed cells.

Claim 38 as currently presented: an oxygen delivery device, comprising a biocompatible, single unit matrix capable of delivering oxygen, comprising; a) a swellable, cross-linked polyacrylamide polymer network, b) deliverable oxygen in closed cells within the cross-linked polyacrylamide polymer network a second reactant and a catalyst reaction occurred, and c) at least one active agent wherein the cross-linked polyacrylamide polymer network is cross-linked prior to oxygen formation, wherein the deliverable oxygen is within the closed cells and is produced by reacting the catalyst with the second reactant to create, where the second reactant and catalyst reaction occurred, multiple closed cells containing deliverable oxygen and with use of the matrix, oxygen is delivered from the closed cells.

Claim 39 as currently presented: a biocompatible, single unit cross-linked polyacrylamide matrix, comprising a swellable, cross-linked polyacrylamide polymer network, and deliverable oxygen in closed cells within the cross-linked polyacrylamide polymer network at sites where a reaction of a catalyst and a second reactant occurred.

Therefore, the present claims 1, 38 and 39 recite a product comprises matrix of closed cell foam of cross-linked polyacrylamide polymer containing oxygen produced by reaction of catalyst and reactant. The limitation of oxygen delivery is directed to intended use that impart patentability to composition claims. The limitation when oxygen

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is produced in the crosslinked polyacrylamide network is directed to process of making the product. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695,698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Determining the scope and contents of the prior art (MPEP§ 2141.01)

Murdock teaches polymeric cross-linked foam reservoir comprising cellulose derivatives and active agent including anti-infective agents and growth factors (abstract; paragraphs 0035, 0049, 0050). The foam reservoir is closed cell foam wherein the closed cells can be produced chemically and contains gasses including oxygen (paragraph 0036).

Marans teaches cross-linked polyacrylamide foam foamed by decomposition product of another polymer during manufacture of the polymer to provide uniform closed cell foam matrix that swells and absorbs water but not dissolve. Foaming of polyacrylamide was performed during the manufacture of the polyacrylamide crosslinked polymer (See the entire document, and especially col.1, lines 12-16, 20-26; col.2, lines 54-59; col.4, lines 6-8).

Ladin teaches wound dressing that supply oxygen to the wound for optimal healing and minimization of infection because the wound causes diffusion limited

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access and limits the oxygen supply to the wound (abstract; col.2, lines 28-31). The dressing comprises polymeric foam comprising elements that react to generate oxygen that are hydrogen peroxide and catalyst such as magnesium dioxide or enzymes (col.6, lines 6-26). The catalyst is contained in the foam which absorbs hydrogen peroxide into the foam to produce oxygen (col.7, lines 48-55). The foam comprises guar gum or polyacrylamide, and further comprises collagen, i.e. non-gellable foam (col.4, lines 39-42; col.12, line 7).

**Ascertaining the differences between the prior art and the claims at issue,
and resolving the level of ordinary skill in the pertinent art (MPEP § 2141.012)**

Although Murdock teaches water swellable closed cell cross-linked polymer foam reservoir, however, Murdock does not explicitly teach polyacrylamide polymer as claimed in claims 1, 38 and 39. Although Murdock teaches closed cell foam containing gas that can be produced chemically, however, the reference does not explicitly teach the specific chemical reaction that produces the gas in the foam as claimed in claims 1, 38 and 39.

Therefore, at the time of the invention it was known to treat wound using closed cell crosslinked polymeric foam containing oxygen that is produced chemically in the foam as taught by Murdock. Cross-linked polyacrylamide closed cell foam was known at the time of the invention to absorb water without dissolving, and it was further known to form uniform crosslinked polyacrylamide foam when foaming is performed during the manufacture of the crosslinked polyacrylamide polymer as taught by Marans.

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Additionally, forming oxygen in a foam matrix by chemical reaction between peroxide and catalyst was known at the time of the invention as taught by Ladin. Furthermore, Ladin taught the benefit of oxygen for the wound.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide polymeric cross-linked closed cell foam wound dressing containing oxygen that can be produced chemically as disclosed by Murdock, and replace the closed cell cross-linked polymer foam with crosslinked polyacrylamide closed cell foam that taught by Marans. One would have been motivated to do so because Marans teaches that cross-linked polyacrylamide closed cell foam can absorb water without dissolving and one would have been motivated to form the bubbles in the crosslinked polymer during the manufacture of the crosslinked polymer because Marans teaches that such process provides a uniform foam. One would have reasonably expected formulating cross-linked polyacrylamide closed cell foam containing oxygen that can be produced chemically wherein the foam is uniform and absorbs water without dissolving. Additionally, it would have been obvious to one having ordinary skill in the art at the time of the invention to produce the crosslinked polyacrylamide closed cell foam containing oxygen in the bubbles as disclosed by the combination of Murdock and Marans, and further produce the oxygen during the formation of the foam by the reaction of hydrogen peroxide and catalyst as disclosed by Ladin. One would have been motivated to do so because Ladin teaches that foam containing oxygen are optimal for wound healing and minimizing infection. One would reasonably expected formulating cross-linked polyacrylamide closed cell foam containing oxygen that is produced

chemically by the reaction of peroxide and catalyst wherein the foam is uniform and absorbs water and further has optimal wound healing effect with minimal infection.

Resolving the level of ordinary skill in the pertinent art (MPEP § 2141.012)

One skilled in the art at the time of the invention would be motivated to prepare wound dressing of closed cell foam of crosslinked polyacrylamide containing oxygen in the bubbles of the foam, wherein the dressing absorb water and deliver oxygen to the wound to optimize its healing and minimize its infection.

It is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. In re Bozek, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been *prima facie* obvious within the meaning of 35 U.S.C. 103 (a) because the invention as a whole is taught by the combined teaching of the cited references.

Response to Arguments

5. Applicant's arguments filed 12/03/2009 have been fully considered but they are not persuasive.

Applicants argue that the closed cells containing gasses taught by US '587 are inert and the gas does not exit the closed cell. "The gas bubbles act as an inert filler, increasing the surface area of the matrix without introducing the drawback of common "inert" fillers, to which therapeutically active agents may bind."

In response to this argument, it is argued that the reference teaches more than one method of foaming including chemical and physical foaming. Physical foaming results into bubbles that act as inert filler. The reference clearly teach the foam is capable for delivering active agents. The limitation of delivery of oxygen from the crosslinked polyacrylamide foam network is directed to the intended use of the foam. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. Delivery of oxygen is taught by Ladin. The combination of the references teaches closed cell foam of crosslinked polyacrylamide containing oxygen in the closed cells, which is the product currently claimed. It is expected that when the product taught by the combination of the prior art is exposed to the same environment, such as wound, culture media, package, etc., the product will behave the same way and react with the environment and release active agents and/or oxygen since materials and their properties are inseparable. The burden is on applicants to show that the closed cell crosslinked polyacrylamide foam containing oxygen in the cells that is taught by the prior art will not deliver oxygen under the same environmental circumstances.

Applicants argue that the '764 patent teaches article of cross-linked polyacrylamide that is foamed by the decomposition product of polyoxymethylene, which is results from the polymerization of acrylamide and trioxane. The foamed product formed is "useful as a packing material, insulation, water absorption material" and there is no teaching or suggestion that the gaseous polyoxymethylene decomposition product is released from the matrix.

In response to this argument, it is argued that '764 patent is relied upon for the solely teaching that polyacrylamide polymers were known at the time of the invention and to show foaming of polyacrylamide during manufacture is known at the time of the invention. Foaming using the claimed catalyst and reactant is taught by Ladin. One would have been motivated to use polyacrylamide because US '764 teaches that cross-linked polyacrylamide closed cell foam can absorb water without dissolving and one would have been motivated to form the bubbles in the crosslinked polymer during the manufacture of the crosslinked polymer because Marans teaches that such process provides a uniform foam.

Applicants argue that the '090 patent does not teach closed cells containing oxygen, and that the dressing of the '090 patent is designed to intermittently generate oxygen in situ for brief periods and the oxygen is immediately provided to the wound.

In response to this argument, it is argued that US '090 is relied upon for teaching forming oxygen in a foam matrix by chemical reaction between peroxide and catalyst and the benefit of oxygen for the wound.

Applicants argue that the '587 publication does not teach the chemical reaction that produces the gas in the foam, nor polyacrylamide polymer as recited in Claims 1, 38 and 39. But, the Office Action concludes that "at the time of the invention it was known to treat wound using closed cell crosslinked polymeric foam containing oxygen that is produced chemically in the foam as taught by Murdock. Applicants argue that the '587 publication is directed to providing a reservoir for an electrotransport drug delivery system, not a wound treatment device or an oxygen delivery device. The closed cells as taught by Murdock" do not function like the currently claimed invention; thus, the "foam as taught by Murdock" is physically and functionally different from Applicants' currently claimed invention.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., wound dressing) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Further, it is argued that US '587 suggested chemical production of gas in cross-linked polymer foam and Marans teaches the specific polymers and Ladin teaches the specific reaction that produced oxygen. The examiner believes that the present invention as a whole is taught by the combination of the cited references.

Applicants argue that the combination of the space-filling closed cells foam reservoir of the '587 publication with the cross-linked polyacrylamide closed cell foam made by the decomposition of polyoxymethylene of the '764 patent does not teach or suggest Applicants' currently claimed invention. The closed cells formed in the '764 patent and the '587 publication do not deliver the gas contained within the closed cells. Both of the references teach inert closed cells that do not change or interact with the environment, and if the closed cells of either reference did interact with the environment and lose the entrapped gas, the volume of the closed cells would be reduced and the product of each reference would no longer be fit for its intended use.

In response to this argument, it is argued that delivery of gas is directed to the intended use of the foam. The combination of the references teaches closed cell foam of crosslinked polyacrylamide containing oxygen in the closed cells, which is the product currently claimed. It is expected that when the product taught by the combination of the prior art is exposed to the same environment, such as wound, culture media, package, etc., the product will behave the same way and react with the environment and release active agents and/or oxygen since materials and their properties are inseparable. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The burden is on applicants to show that the closed cell crosslinked polyacrylamide foam containing oxygen in the cells

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that is taught by the prior art will not deliver oxygen under the same environmental circumstances.

Applicants are questioning where in the method of the '764 patent would a catalyst be added? Is the catalyst added to the liquid and the hydrogen peroxide added to the liquid? Does any oxygen evolved interfere with the polymerization? What effect does the irradiation and heating have on the catalyst or the hydrogen peroxide? Is the hydrogen peroxide added, before or after the second heating step to decompose the polyoxymethylene? What effects does polyoxymethylene have on a catalyst or hydrogen peroxide? Not only would the cited references not lead one to consider these questions, the answers to such questions are not obvious from the teachings of the references. The teaching of the combination of the '587 publication and the '764 patent are that the closed cells are inert and no gas leaves the closed cells, so even if the closed cells contained oxygen made chemically as taught by the '090 patent, the oxygen would not be released.

In response to applicants' question, as indicated repeatedly supra, US '764 is relied upon for teaching the type of polymer used to form the crosslinked foam, which is polyacrylamide, and to show that at the time of the invention it was known to use crosslinked polyacrylamide polymer to form closed cell foam wherein foaming is done during the process of manufacture of the foam, as taught by US '764. It is further noted that all applicants' questions are directed to the method of making the foam taught by US '764, however the present claims are directed to a product. It has been held that

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even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695,698, 227 USPQ 964, 966 (Fed. Cir. 1985). Cross linking of the polymer matrix before or after addition of oxygen does not impart patentability to the claims because it has been held that it is prima facie obvious to reverse the order of the prior art process steps, *Ex parte Rubin*, 128 USPQ 440 (Bd. App. 1959). See also *In re Burhans*, 154 F.2d 690,69 USPQ 330 (CCPA 1946), selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results; *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930), selection of any order of mixing ingredients is prima facie obvious.

Further, the combination of US '587 and US '764 teaches product comprising oxygen within closed cell foam of cross-linked polyacrylamide matrix, and US '764 further teaches **to form uniform crosslinked polyacrylamide foam when foaming is performed during the manufacture of the crosslinked polyacrylamide polymer**. US '090 teaches the use of cross-linked polyacrylamide and the chemical reaction that produces the oxygen. Therefore, the combination of the references would teach cross-linked polyacrylamide matrix comprising closed cells containing oxygen produced by the chemical reaction between catalyst and reactant as instantly claimed. The invention as a whole is taught by the combination of the references. If the product taught by the

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combination of the prior art is exposed to environmental circumstances such as wound, culture media, to form a package, etc., it will behave the same way as the present product since it has the same elements. The burden is on applicants to show that the closed cell crosslinked polyacrylamide foam containing oxygen in the cells that is taught by the prior art will not deliver oxygen under the same environmental circumstances.

Applicants argue that the '587 publication teaches "foaming a polymeric solution", and not foaming a cross-linked polymeric network. In the embodiments taught by the '587 publication, the gas of the polymer matrix in the '587 publication is introduced into the composition when the polymer solution is a liquid, and before the polymer solution is cross-linked.

In response to this argument, applicants' attention is drawn to the scope of the present claims that is directed to a product comprising cross-linked matrix containing oxygen in closed cells. US '587 teaches polymeric cross-linked foam reservoir comprising cross-linked polymer and closed cell containing oxygen that can be produced chemically. US '587 suggests chemical formation of gas in the closed cells. US '764 teaches **to form uniform crosslinked polyacrylamide foam when foaming is performed during the manufacture of the crosslinked polyacrylamide polymer.** US '090 teaches the chemical reaction that produce oxygen in polyacrylamide foam. Regarding process of making the product, it has been held that even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its

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method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695,698, 227 USPQ 964, 966 (Fed. Cir. 1985). Cross linking of the polymer matrix before or after addition of oxygen does not impart patentability to the claims because it has been held that it is prima facie obvious to reverse the order of the prior art process steps, *Ex parte Rubin*, 128 USPQ 440 (Bd. App. 1959). See also *In re Burhans*, 154 F.2d 690,69 USPQ 330 (CCPA 1946), selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results; *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930), selection of any order of mixing ingredients is prima facie obvious. Applicants failed to show superior and unexpected results obtained from cross-linking before forming oxygen or after forming oxygen in the matrix. Additionally, regarding the order of steps, it is argued that US '587 teaches product comprising oxygen within the cross-linked matrix, and US '090 teaches the use of cross-linked polyacrylamide and the chemical reaction that produces the oxygen, therefore, the combination of the references would teach cross-linked polyacrylamide matrix comprising closed cells containing oxygen. The invention as a whole is taught by the combination of the references.

Applicants argue that there is no suggestion or motivation to make the proposed modification of a polyacrylamide polymer of the '764 patent in the foam of the '587 publication, and in fact, the '587 publication teaches away from use of polyacrylamide

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by requiring the gas be introduced into a liquid polymer solution prior to the cross-linking of the polymer solution. Modification of the '587 publication by implementation of polyacrylamide polymer to create a polyacrylamide foam matrix as taught in the '764 patent would render the '587 publication unsatisfactory for its intended purpose.

Modification of the '764 patent by implementation of the method of the '587 publication would render the '764 patent unsatisfactory for its intended purpose. The modification of the addition of the production of oxygen as taught by the '090 patent to either the '764 patent or the '587 publication, individually or in combination, does not result in a product that is satisfactory for its intended purpose. Further, the intended purpose of the closed cell foams of the '587 publication and the '764 patent are that the closed cells are inert and the foam product maintains its structure by not delivering the gas contained within the closed cells. There is no teaching of a modification of any of the cited references to render the closed cells of the cited references anything other than to be inert, and if such a modification is attempted, it would render the combined references unsatisfactory for their intended purposes.

In response to these argument, applicants' attention is directed to the scope of the present claims that are directed to a product by process, and the patentability of the claims is determined by the product, as set forth in this office action. US '587 clearly teaches in paragraph 0036 "foaming a polymer matrix....by any physical or chemical methods known in the art". Introduction of the gas to polymer solution taught by US '587 is a preferred method of making embodiment. The disclosed examples and preferred embodiment do not constitute a teaching away from a broader disclosure or

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nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). US '587 does not teach away from the present invention as it is directed to closed cell foam polymer containing oxygen used for wound treatment. "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant. The degree of teaching away will of course depend on the particular facts; in general, a reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant." *In re Gurley*, 27 F.3d 551,553 (Fed. Cir. 1994). In this case US '587 does not deter one having ordinary skill in the art from using closed cell foam polymer containing oxygen for wound treatment. US '587 is an analogous art and in the field of applicant's endeavor and reasonably pertinent to the particular problem with which the applicant was concerned, which is wound treatment. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). Applicants' attention is further directed to US '764 that teaches to **form uniform crosslinked polyacrylamide foam when foaming is performed during the manufacture of the crosslinked polyacrylamide polymer** and US '090 that teaches method for **chemical generation of oxygen using catalyst and peroxide that is suitable for wound dressings and also teaches polyacrylamide matrix containing the oxygen**. The invention as a whole is taught by the combination of US '587, US '764 and US '090. An article comprising cross-linked polyacrylamide matrix and oxygen in closed cells as claimed would have been obvious to one skilled in the art at the time the

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invention was made because the prior art recognized cross-linked polymeric matrix containing oxygen in closed cell delivered chemically and also recognized the suitability of polyacrylamide and the oxygen generation from reaction off catalyst and peroxide in wound dressing. It has been held that "When a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR Int 'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. AG Pro, Inc.*, 425 U.S. 273,282 (1976)). "When the question is whether a patent claiming the combination of elements of prior art is obvious," the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions."

Applicants traverse the Office Action statement that "If the prior art structure is capable of performing the intended use, then it meets the claim. Applicants argue that the prior art structure, either that of the '587 publication or the '764 patent, is incapable of delivering a gas from its closed cells, and if either of them suffered a loss of gas from the closed cells, with the concomitant loss of volume of the closed cells, the entire function of the structure would be destroyed.

In response to this argument that, it is argued that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. US '587 is directed to wound treatment as intended by the present

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invention. If the product taught by the combination of the prior art is exposed to environmental circumstances such as wound, culture media, to form a package, etc., it will behave the same way as the present product since it has the same elements. The burden is on applicants to show that the closed cell crosslinked polyacrylamide foam containing oxygen in the cells that is taught by the prior art will not deliver oxygen under the same environmental circumstances.

Applicants argue that hindsight is being used to combine terms that are found in the prior art, without a consideration of the physical and chemical realities of the terms, to try to reach a teaching or suggestion of Applicants' currently claimed invention.

In response to this argument, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). All the elements of the present invention are taught by the prior art and were known at the time of the invention, further there were motivation to combine the references as set forth in this office action.

Applicants argue that the Office Action fails to consider that reversing the order of steps may be possible if the order of steps is not important to the result or are not

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limited by the chemical or physical nature of the components used in the method.

Formation of a polyacrylamide matrix with closed cells containing oxygen wherein the oxygen is delivered from the closed cells occurs if the polyacrylamide matrix is first cross-linked, and oxygen is introduced into the matrix following cross-linking of the polyacrylamide polymers, and the resulting closed cells deliver the oxygen found within the closed cells. The cited references never teach a method for making closed cell foams where the gas is delivered from the closed cells. Adding the oxygen first and then cross-linking the polymers is not chemically possible for polyacrylamide, and if another polymer is used, as in the '587 publication, the cells produced do not deliver the gas. Replacing polyoxymethylene with oxygen in the '764 patent cannot be accomplished using the methods taught by the '764 patent, and merely stating that it can be done is not the standard for obviousness. Additionally, only in Applicants' claimed invention do the closed cells deliver the gas, and not in the teachings of the cited references. Given the technical limitations associated with cross-linking polyacrylamide in the presence of oxygen, the manufacturing process steps imparting distinctive structural characteristics to the final product and must be considered when assessing the patentability of the claims. The statements of the Office Action cited for supporting prima facie obviousness are not applicable to the currently pending invention.

In response to this argument, it is argued that cross-linked polymer matrix is taught by US '587, but US '587 does not specifically teach polyacrylamide that was known at the time of the invention and taught by US '764. US '764 further teaches to form uniform crosslinked polyacrylamide foam when foaming is performed during the

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manufacture of the crosslinked polyacrylamide polymer. US '090 is relied upon for the teaching of catalyst/peroxide reaction to produce oxygen in a wound dressing matrix made of polyacrylamide. Further, US '090 teaches advantage of dressing comprising polyacrylamide polymer and oxygen generated from the reaction of catalyst and peroxide to supply oxygen to the wound for optimal healing and minimization of infection. The teaching of US '090 would have been motivated one having ordinary skill in the art at the time of the invention to replace the polymer matrix disclosed by US '587 with polyacrylamide matrix and create oxygen by the reaction of catalyst and peroxide as taught by US '764 and US '090.

To summarize, at the time of the invention it was known to treat wound using closed cell crosslinked polymeric foam containing oxygen that is produced chemically as taught by US '587. **Cross-linked polyacrylamide closed cell foam** was known at the time of the invention to absorb water without dissolving, and it was further known to form uniform crosslinked polyacrylamide foam when **foaming is performed during the manufacture of the crosslinked polyacrylamide polymer** as taught by US '764. Additionally, **forming oxygen in a foam matrix by chemical reaction between peroxide and catalyst** was known at the time of the invention as taught by US '090. Furthermore, Ladin taught the benefit of oxygen for the wound.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide polymeric cross-linked closed cell foam wound dressing containing oxygen that can be produced chemically as disclosed by Murdock, and replace the closed cell cross-linked polymer foam with crosslinked polyacrylamide

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closed cell foam that taught by Marans. One would have been motivated to do so because Marans teaches that cross-linked polyacrylamide closed cell foam can absorb water without dissolving and one would have been motivated to form the bubbles in the crosslinked polymer during the manufacture of the crosslinked polymer because Marans teaches that such process provides a uniform foam. One would have reasonably expected formulating cross-linked polyacrylamide closed cell foam containing oxygen that can be produced chemically wherein the foam is uniform and absorbs water without dissolving. Additionally, it would have been obvious to one having ordinary skill in the art at the time of the invention to produce the crosslinked polyacrylamide closed cell foam containing oxygen in the bubbles as disclosed by the combination of Murdock and Marans, and further produce the oxygen during the formation of the foam by the reaction of hydrogen peroxide and catalyst as disclosed by Ladin. One would have been motivated to do so because Ladin teaches that foam containing oxygen are optimal for wound healing and minimizing infection. One would reasonably expected formulating cross-linked polyacrylamide closed cell foam containing oxygen that is produced chemically by the reaction of peroxide and catalyst wherein the foam is uniform and absorbs water and further has optimal wound healing effect with minimal infection.

One skilled in the art at the time of the invention would be motivated to prepare wound dressing of closed cell foam of crosslinked polyacrylamide containing oxygen in the bubbles of the foam, wherein the dressing absorb water and deliver oxygen to the wound to optimize its healing and minimize its infection.

It is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. In re Bozek, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter as a whole as defined by the claims would have been *prima facie* obvious within the meaning of 35 U.S.C. 103 (a) because the invention as a whole is taught by the combined teaching of the cited references.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Isis A Ghali/
Primary Examiner, Art Unit 1611

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